

## EXHIBIT 409

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**From:** Ducca, Anita  
**Sent:** Thursday, January 10, 2008 9:06 PM  
**To:** 'BILL WILSON'  
**Subject:** FW: Suspicious Orders Business Procedures  
**Attachments:** Customer Verifications Procedure R-07.01.pdf; Requirements for CustoeMr Drug Purchases R-03.02.pdf; Control Drug Compliance Reconciliation Procedure R-03.04.pdf; Controlled Substance Monitoring & Reporting Procedures R-03.07.pdf; A Suspicious Order Monitoring Overview update 6-2007.doc; Review Suspicious Orders.doc

**Importance:** High

Bill, all week, we have been contacting our members to request their suspicious orders information. this is the first of a few e-mails I'll be sending with what we have received so far. This is from our member Henry Schein, Inc. This company specializes in sales to individual practitioners as opposed to pharmacies. Their concern will be that their business model is very different from other wholesale distributors who sell to pharmacies and hospitals.

Anita

---

**From:** Cherico, Brian  
**Sent:** Thursday, January 10, 2008 10:08 AM  
**To:** Ducca, Anita  
**Subject:** Suspicious Orders Business Procedures  
**Importance:** High

Anita,

I just received these attachments from Henry Schein. I have only scanned them briefly, but they look like they may be of some value.

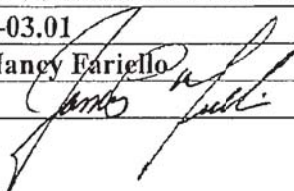
Brian

.....  
Brian M. Cherico, Esq.  
Manager, Regulatory Affairs & Healthcare Policy  
Healthcare Distribution Management Association  
(703) 885-0257  
Fax: (703) 935-3200  
[www.HealthcareDistribution.org](http://www.HealthcareDistribution.org)

.....  
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QUALITY STARTS WITH US...

Title: Customer Verifications Procedure	
Document #: R-03.01	Page: 1 of 9
Prepared By: Nancy Fariello	Revised: Rev. 4 April 9, 2003
Approved By: 	Original Issue: Feb. 5, 1998

1. **PURPOSE:**

The purpose of this document is to define the verification of customer's licenses to purchase prescription and controlled drugs.

2. **SCOPE:**

This document applies to all Verifications TSM.

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3. **DEFINITIONS:**

See Page 4

4. **RESPONSIBILITY:**

All Verifications TSMs

5. **RELATED DOCUMENTS:**6. **RECORDS GENERATED:**

Certification by Foreign Customer – Appendix A – Maintained for a minimum of 2 years by the International Order Dept.

7. **ATTACHMENTS:**

DEA authorization letter regarding *addition* of corporate name – Attachment A

DEA authorization letter regarding *change* of corporate name – Attachment B

DEA authorization letter regarding *change* of corporate name for 222 form – Attachment C

DEA authorization letter regarding zip codes – Attachment D

8. **PROCEDURE:**

See attached pages



*QUALITY STARTS WITH US...*

<b>Title:</b> Customer Verifications Procedure	<b>Page:</b> 2 of 9
<b>Document #:</b> R-03.01	<b>Revised:</b> Rev. 4 April 9, 2003
<b>Prepared By:</b> Nancy Fariello	<b>Original Issue:</b> Feb. 5, 1998

<b>REVISION HISTORY</b>	
Rev. 1	Drug Order Verification & Suspicious Orders sections re-written to clarify procedures, replaced DEA license to DEA registration and revised format. <b>Issued: 03/19/01</b>
Rev. 2	Page 4-changed responsibility to Inventory Management Analyst & Compliance Coordinator. Re-arranged process steps. <b>Issued 10/16/02</b>
Rev. 3	Changed name and updated and restructured entire procedure. <b>Issued: 3/7/03</b>
Rev. 4	Added definitions for: Controlled Substances, Prescription devices and drugs, NSI, 222 Form, Mid Level Practitioner and section 8 for Nevada 10% Regulation. <b>Issued: 4/9/03</b>

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### Definitions

<b>DEA:</b>	Drug Enforcement Administration
<b>Rx:</b>	Prescription Drug or Device
<b>Prescription Drugs &amp; Prescription Devices:</b>	Any drug or device unsafe for self-use, including the following: a) Any drug that bears the legend: "Caution: Federal law prohibits dispensing without prescription" or word of similar import. b) Any device that bears the statement: "Caution: Federal law restricts this device to sale by or on the order of a _____," or word of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device. c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription.
<b>Controlled Substance:</b>	Drugs determined by the DEA to have the potential for abuse. These drugs are classified as schedules/classes I through V by the DEA.
<b>222 Form</b>	Federal 222 triplicate order form used to order Controlled Substances in DEA Schedules II and II-N.
<b>NTIS:</b>	National Technical Information Service
<b>TSMs:</b>	Team Schein Members
<b>JDE:</b>	JD Edwards Computer Program
<b>Hard Documentation:</b>	License verification by one of the following: 1. Exact address match on photocopy of State License or Federal DEA 2. Exact address match in professional directory, or online 3. Exact address match on NTIS tape 4. Documented verbal verification with state or federal agency
<b>Government Institution:</b>	Veterans Administration, Federal, State, Local Agency
<b>Large</b>	
<b>Non-Government Inst.:</b>	Universities, Colleges, Hospitals, etc.
<b>Small</b>	
<b>Non-Government Inst.:</b>	Elementary or High Schools, Nursing Homes, Large & Small Medical Industrial Dept.
<b>Mid Level Practitioner:</b>	An individual practitioner other than a physician, dentist, veterinarian or podiatrist. Examples include Certified Advanced Practice Nurses, Nurse Practitioner; Midwife; Physician's Assistant, and other persons authorized by state law to dispense controlled substances.
<b>NSI</b>	Non-stocking item.

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## 1. Controlled Substance Orders

Only customers registered with the Federal DEA may order Controlled substances.

### 1.1 The following criteria must be met for all controlled substance orders:

- 1.1.1 First time customers must submit a hard copy of their federal DEA registration certificate. To ensure that the hard copy has the most current information, verification of the registration is done via the NTIS tape as well;
- 1.1.2 NTIS tape will be used for subsequent DEA verifications;
- 1.1.3 The DEA registration must be current;
- 1.1.4 The name & address of the controlled substance shipment must match the DEA certificate (no re-direction or "attention to" is permitted);
- 1.1.5 The drug schedules being ordered must match the registered schedules. Note, Researchers, Analytical Labs, and Wholesalers may order schedule 2N if they are registered for schedule 2;
- 1.1.6 If the DEA certificate has a PO box and a physical address, we must ship to the physical address, using the physical address zip code;
- 1.1.7 If the DEA has only a PO box DO NOT SHIP THE ORDER. Verifications rep will call the doctor and instruct him to amend his certificate to include the physical delivery address;
- 1.1.8 The DEA certificate may not be altered in ANY way.

### 1.2 Variations in DEA Certificates for which HSI has gotten DEA approval for shipment:

- 1.2.1 As long as the shipping address is the same as the DEA certificate address, HSI may add a corporation name to the customer's account even though the DEA certificate does not include that corporate name (attachment A);
- 1.2.2 If the registration is under a doctor's name and his corporation name has changed, but the doctor's name and shipping address is the same, HSI may change the corporation name on the account and keep the DEA number active. This holds true for the 222 forms as well (attachments B & C).

**Examples:** 1. DEA Certificate reads: John Smith DVM  
ABC Vet Hospital  
123 Main Street  
Melville, NY 11747

2. Corp. name changed to: John Smith DVM  
DEF Vet Hospital  
123 Main Street  
Melville, NY 11747

Instruct the doctor to amend his/her certificate and 222 forms as soon as possible (however we can ship the order).

**NOTE:** *If the registration is under the corporation name and the corporation name or the doctor's name has changed, DO NOT SHIP the order. The DEA registration must be amended.*

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1.2.3 For differing zip codes use the following guidelines (attachment D):

- a. If the zip code is incorrect due to a re-structuring of zip code areas by USPS, and the physical address remains the same, use the new correct zip code and ship the controlled substance order;
- b. If the zip code is incorrect due to a customer or DEA error and the first 3 digits match the zip code of the shipping address, use the correct zip code and ship the controlled substance order;

In both above cases the customer must be instructed to have his/her DEA certificate corrected.

## 2. Rx Orders

2.1 In order to ship Rx items to a customer, the customer must be a licensed practitioner. A licensed practitioner is one who is authorized by the state to purchase, possess, prescribe, and dispense prescription drugs. The shipping address of the customer must also be verified.

### 2.2 Customer Provided Documentation

- 2.2.1 Either of these three documents may be used provided the license is registered in the same name, and address as the customer:
- a. Photocopy of DEA Certificate
  - b. Photocopy of State License
  - c. Photocopy of State Controlled Substance Registration

\*\*\*\*\* ALL *Florida customers*, when ordering Rx drugs, must have their Florida Department of Health license number and expiration date on their account even if they have a DEA registration.

### 2.3 Schein Obtained Documentation

- 2.3.1 Either of these three sources may be used to verify the address and licensure of the customer:
- a. Exact name and shipping address match on the NTIS tape;
  - b. Exact name and shipping address match in physician directory or software;
  - c. Exact name and shipping address match with State Board, on-line or by phone.

### 2.4 Linking

2.4.1 First Time Customers - If all of the above types of verification do not provide an exact match of the shipping address, you must obtain a hard-copy of the doctor's state license. If the hard copy address does not match the shipping address you may confirm the shipping address by phone or internet. Document your conversation in the microfilm screen.

- 2.4.2 Repeat Customers - If all of the above types of verification do not provide an exact match of the shipping address, but does match BOTH the name and state of the customer, you may use the following in COMBINATION with the above licensure and state verification of the customer:
- a. Confirmation of the shipping address under the doctor's professional office is done by phone or internet; Document your conversation in the microfilm screen.

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### 3. Institutions

#### 3.1 Controlled Substance Orders

To ship controlled substances to **any** institution as listed below, a current DEA with the exact shipping name and address of the institution, or the exact name and address of the authorizing doctor as registered on his DEA must be on the account.

#### 3.2 Rx Orders

To ship orders containing Rx products, please refer to the appropriate heading below.

##### 3.2.1 Government Institutions

- a. If a Government agency (Federal, State or Local) places an order for Rx drugs on an official purchase order (hard copy), the order can be shipped without any further verification.
- b. If a Government agency places an order for Rx drugs by phone to an existing account for which we have shipped merchandise and received payment, and the order has a PO number consistent with the historical sequence, the order can be shipped without any further verification.
- c. Orders received from Government agencies which do not meet the criteria listed above, are required to document their authority to order Rx items either by "hard documentation" or by an authorizing doctor's letter. Refer to section "F", Ship & Add Letter.

##### 3.2.2 Large Non-Government Institutions (Universities, Colleges, Hospitals)

- a. If "large" non-government institutions place an order for Rx products which are consistent with the purpose of the institution, the Rx items can be shipped. This will allow dental institutions to order dental products, medical institutions to order medical products, etc. If the order contains non-related products, the validity of the order should be verified with the purchasing department of the institution and they must document their authority to order Rx items either by "hard documentation" or by an authorizing doctor's letter. Refer to section "F", Ship & Add Letter.

##### 3.2.3 Small Non-Government Institutions (Elementary or High School, Nursing Homes, Large & Small Medical Industrial Dept)

- a. If "small" non-government institutions place an order for Rx products they are required to provide "hard documentation" of the doctor who is authorizing Rx purchases. Refer to section "F", Ship & Add Letter.

##### 3.2.4 Pharmaceutical Wholesalers

- a. All sales of Rx items to pharmacy wholesale accounts should be supported by "hard documentation".
- b. Multiple addresses must be verified by "hard documentation".

##### 3.2.5 Retail Pharmacies

- a. Sales of Rx drugs to retail pharmacies is limited to those who are listed in the State's Professional License website or have furnished a copy of their DEA or state license.
- b. Multiple addresses must be verified by "hard documentation".

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### 3.2.6 Ship & Add Letter

- a. A Ship & Add letter is written to institutional accounts and accounts under business names (when the doctor's registered address differs from the institutional or business physical address) to obtain authorization from the doctor who is responsible for purchasing and dispensing Rx products for that account. Before the doctor is added to the account verifications representative will determine if the doctor is licensed in that state.
- b. In order for HSI to process future orders without hold-up, the authorizing doctor must respond to the letter and submit his/her state or federal license.
- c. After receiving the signed letter and the state or federal license of the doctor in charge, the account will be updated for one year from the end of the current month, unless the actual license expires before that time. If the license expires in less than a year, the actual expiration date on the state license will be used. Example: If the license expires in three months, the account is updated for three months. If the license expires in two years the account is updated for **one** year.
- d. Verifications will send a maximum of three Ship & Add letters *or* allow up to six months (whichever comes first) for the doctor to send the required documents. If the required documents are not received after the 3<sup>rd</sup> letter or within 6 months of the first order, no further Rx orders will be shipped.

### 4. HMOs

- 4.1 HMOs must have the name of a responsible doctor in charge on the account. The doctor must be verified in that state. If the license cannot be verified, the HMO must be called for another doctor's name. No HMO orders will be shipped without a verified responsible doctor.

### 5. Mid-Level Practitioners

*All orders for Mid-Level Practitioners which contain RX & Controlled products will pend to verifications every time an order is placed.*

- 5.1 After verification is made that an order for a controlled substances can be released, the schedules will be removed on the DEA verification, forcing subsequent controlled substance orders to pend. Subsequent Rx orders will automatically pend, as the state license information is not updated at the time the Rx order is over-ridden.
- 5.2 The Regulatory Department will print an updated copy of the Mid-Level Practitioners Authorization by State from the internet and distribute it to the Lead Verifications Rep twice yearly.

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## **6. Government Customer Purchase Inquiries**

- 6.1 Inquiries may be received via mail, fax or telephone call from an individual seeking information on drug or medical device purchases. Most often, the inquiry concerns customer purchases of Class II-V drugs (controlled substances).
- 6.2 All inquiries involving governmental officials or in response to a subpoena concerning drug purchases made by HSI customers should be handled as outlined below:
  - a. No information is given out over the telephone
  - b. All outside parties should be instructed to put their request in writing on their agency or office letterhead
  - c. Inquiries should be forwarded to the Verifications Supervisor or Customer Service Manager, Melville, New York.
  - d. If possible, the inquiry should state the professional's DEA #, address, and the time period for the requested information.
  - e. All HSI staff should refrain from giving their opinion as to drug quantities ordered combinations of drugs, etc.

## **7. International Rx Orders**

- 7.1 All international customers wishing to order Rx products must complete the "Certification by Foreign Customer" form. This form will be sent by International Order Department to customers and completed forms are maintained by the International Order Department.

## **8. Nevada 10% Regulation**

- 8.1 Nevada Regulations prohibit wholesalers from shipping prescription drug orders, in any given month, totaling more than 10% of HSI's inventory to wholesale or distributor customers located in Nevada. Prescription drug orders placed for more than 10% of our inventory will pend to verifications.
- 8.2 Verifications TSM will contact sales TSM responsible for the order and notify them of the pending order.
- 8.3 Sales TSM will determine resolution with their appropriate manager. Resolution may include:
  - a. Reducing the amount of product ordered;
  - b. Deleting the entire product from the order;
  - c. Releasing order as is; with responsible manager's authorization.
- 8.4 Sales TSM or manager will get back to verifications TSM with resolution. If verifications TSM determines that the resolution may not be appropriate they should contact Regulatory Affairs for final resolution.
- 8.5 Drop ship orders are shipped to customers directly from supplier's inventory. NSI orders are filled with inventory specifically obtained for that particular order and never becomes part of regular sellable inventory. Therefore, this regulation does not apply to drop ship or NSI orders.

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U. S. Department of Justice  
Drug Enforcement Administration

Washington, D.C. 20537

DEC 07 1999

Ms. Nancy Fariello  
Henry Schein, Incorporated  
135 Buryea Road  
Melville, New York 11747

Dear Ms. Fariello:

This is in response to your fax dated November 15, 1999, and subsequent telephone conversation with Program Analyst Vickie Seeger. You requested guidance on the appropriateness of adding a corporation name to a registrant's shipping address even though the corporation name is not on the registrant's Drug Enforcement Administration (DEA) Certificate of Registration. The scenario described specified that the practitioner's physical practice location, as indicated on the DEA registration, is the same as the shipping address.

The DEA requires that all shipments of controlled substances be shipped to the address of record of the registrant. In your example, controlled substances are being shipped to the address on the registrants' DEA certificate. The addition of a corporation name on a shipping address is allowable as long as the registrant's name is on the shipping label and the physical address is the same as that on the DEA registration certificate.

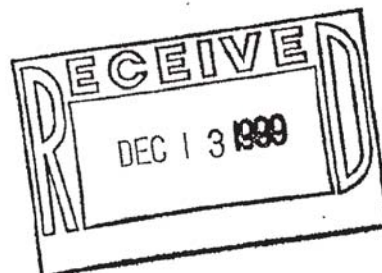
I trust this response is adequate. Should you need additional information please telephone Ms. Seeger at (202) 307-7283.

Sincerely,

*Patricia M. Good*  
Patricia M. Good, Chief  
Liaison and Policy Section  
Office of Diversion Control

cc: DPMs

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Attachment A





## U. S. Department of Justice

Drug Enforcement Administration

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Washington, D.C. 20537

MAY 6 5 1999

Ms. Nancy Fariello  
Henry Schein, Incorporated  
135 Duryea Road  
Melville, New York 11747

Dear Ms. Fariello:

This is in response to your letter dated March 29, 1999, and subsequent telephone conversation with Staff Coordinator Christopher Grush. You requested guidance on the appropriateness of shipping Schedule III-V controlled substances to a practitioner who is in the process of amending a DEA certificate to reflect a name change.

A practitioner registrant authorized to handle controlled substances is required to report any change of professional or business address to the Drug Enforcement Administration. In the example you provide, Joseph Smith, DVM, who is the practitioner registrant and responsible party for ABC Veterinary Clinic, has requested the clinic's name be changed to DEF Veterinary Clinic. Since DEA registers the individual practitioner, not the veterinary clinic, the example does not actually reflect a change of the registrant's name or physical location. There is therefore, no restriction on shipping controlled substances pending amendment of the DEA registration certificate.

Hopefully, this information has been helpful to you. If you have any additional questions or concerns, please feel free to contact this office at (202) 307-7296.

Sincerely,

*Patricia M. Good*

Patricia M. Good, Chief  
Liaison and Policy Section  
Office of Diversion Control

CC: Margaret Brophy, DPM  
New York Field Division

Attachment B

202 307 8570

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## FAX TRANSMITTAL SHEET

DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

NOTE: If you have any problems with this transmission (incorrect number of pages/poor quality), call the transmitter and request retransmission.

NUMBER OF PAGES BEING TRANSMITTED  
(Including this transmittal sheet)

1

TRANSMITTED TO	FAX FTS NO.	FAX COMMERCIAL NO. 516-843-5557
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NAME:

Nancy Fariello

ORGANIZATION:

Henry Schein

BUILDING, ROOM NO., etc.

TELEPHONE/EXTENSION

TRANSMITTED FROM	FAX FTS NO.	FAX COMMERCIAL NO. 317/226-7703
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NAME:

Donald L. Hickman

ORGANIZATION:

DEA/Diversion - Indianapolis District Office

BUILDING, ROOM NO., etc.

TELEPHONE/EXTENSION

317/226-6791

COMMENTS:

Dear Nancy,

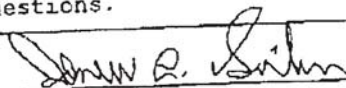
Regarding our telephone conversation today please let this fax serve as authorization

for Henry Schein to do the following in Indiana:

1. When processing orders for controlled substances (including CII's) and the practitioner has changed the name of his business but not his address or his DEA number, to ship to him using his old order forms.

2. To use his new name when filling orders before receipt of the new order forms.

Please call if you have any questions.



Donald L. Hickman

APPROVED BY (If applicable)

NAME:

TRANSMITTED BY (Name):

DATE:

TIME:

DEA Form  
(Dec. 1991) • 501

317 226 7703

PAGE.001

Attachment C



Drug Enforcement Administration

# UNCONTROLLED COPY

Washington, D.C. 20537

JAN 15 1999

Ms. Nancy Fariello  
Regulatory Affairs Department  
Henry Schein, Inc.  
135 Duryea Road  
Melville, New York 11747

Dear Ms. Fariello:

This is in response to your inquiries concerning the applicability of Title 21 of the Code of Federal Regulations Part 1305.09(c) [21 CFR 1305.09(c)] in situations where the U.S. Postal Service (USPS) has made changes to postal zip codes. As you know, 21 CFR 1305.09(c) requires that controlled substances be "shipped to the purchaser and at the location printed by the Administration on the order form". You ask whether the use of a newly issued zip code (which differs from the zip code appearing on the official DEA form 222) on shipping labels conflicts with this mandate.

In the situation in question, the change reflects a general restructuring of zip code areas by USPS. There is no change to the physical location or address of the DEA registrant/purchaser. Placing the correct zip code on the shipping label would not constitute shipping the order to an address other than the one at which the purchaser is registered; it would instead insure that it is delivered correctly.

For the past year the Office of Diversion Control's (OD) Registration and Program Support Section (ODR) has been attempting to make the appropriate changes systematically based on the information from USPS or from registrants directly. However, our efforts have and will continue to lag behind the actual zip code changes.

Attachment D  
1 of 2



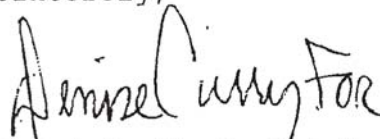
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Ms. Nancy Fariello

Page 2

We appreciate your efforts in making us aware of this issue.  
If you have any questions, please contact Program Analyst Anne Belk  
at (202) 307-4875.

Sincerely,

A handwritten signature in cursive script, appearing to read "Patricia Good", written over the typed name.

Patricia Good, Chief  
Liaison and Policy Section  
Office of Diversion Control

Attachment D  
2 of 2